

In re Application of:  
Carson and Albani  
Application No.: 09/616,247  
Filed: July 14, 2000  
Page 4

PATENT  
Attorney Docket No.: UCSD1370-5

### REMARKS

#### Regarding the Amendments

Claims 10, 18, 19 and 22-24 have been amended as set forth in the above complete listing of the claims. As amended, the claims are supported by the specification and the original claims. By the present amendment, cancellation of claims 20 and 21 is requested, without prejudice. No claims have been added. Thus, upon entry of the amendments, claims 10, 18, 19, 22-24 and 32 will be pending.

#### Rejection Under 35 U.S.C. § 112

Applicants respectfully traverse the rejection of claims 10 and 18-24 under 35 U.S.C. § 112, second paragraph as allegedly indefinite for failing to point out and distinctly claim the subject matter of the invention.

In particular, claim 18 is rejected as reciting the term "the polynucleotide of claim 32." The Examiner's attention is respectfully drawn to amended claim 18, which no longer contains this term. The amended claim is directed to "[t]he vector of claim 32," which contains sufficient antecedent basis in claim 32. Therefore, claim 18 meets the definiteness requirement of 35 U.S.C. § 112, second paragraph. Withdrawal of the rejection is therefore requested. It is noted that claim 19 has been amended similarly.

Additionally, claims 23 and 24 are rejected as unclear. Specifically, the Examiner states that claim 23 recites "the polynucleotide...further comprising an immunomodulatory compound..." and that claim 24 recites "...wherein the immunomodulatory compound is TGF- $\beta$ ..." The Examiner's attention is drawn to the complete listing of the claims, as set forth above. It is noted that claims 23 and 24 have been amended, such that each recites that the vector further comprises a composition in combination with an immunomodulatory compound.

In re Application of:  
Carson and Albani  
Application No.: 09/616,247  
Filed: July 14, 2000  
Page 5

PATENT  
Attorney Docket No.: UCSD1370-5

Accordingly, Applicants respectfully submit that the claims are clear and request withdrawal of the rejection.

**Rejection Under 35 U.S.C. § 102**

Applicants respectfully traverse the rejection of claims 10, 18, 22 and 32 under 35 U.S.C. 102(b) as allegedly anticipated by Bardwell, as evidenced by Accession No. HHECDJ. It is stated in the Office Action that the claimed compositions are anticipated by Bardwell because "Bardwell et al. teach an isolated polynucleotide produced by *E. coli* which encodes dnaJp1 having the amino acid sequence of SEQ ID NO: 4."

A *prima facie* rejection of a claim for anticipation requires that the cited reference describe, explicitly or inherently, all of the elements of the rejected claim. Here the cited reference fails to anticipate any of the pending claims because it does not teach or suggest a bacterial dnaJ peptide, the amino acid sequence of which consists essentially of SEQ ID NO: 4.

Applicants respectfully submit that Accession No. HHECDJ is the full length amino acid sequence of the protein *E. coli* K12 dnaJ. Claim 10 of the claimed invention recites an isolated polynucleotide which encodes bacterial dnaJp1 peptide with the specific amino acid sequence of SEQ ID NO: 4. While the full length nucleic acid sequence encoding Accession No. HHECDJ is set forth in Figure 2 of Bardwell, et al., the reference does not teach oligonucleotide portions of that nucleotide sequence. As such, it is submitted that the cited art is relevant only with respect to the full length K12 dnaJ amino acid sequence. Where the nucleic acid sequence encoding Accession No. HHECDJ includes a portion that encodes SEQ ID NO: 4 of the claimed invention, it is at positions 181-225 in the middle of the 1232 nucleotide full length sequence. In contrast, claim 10 recites an isolated polynucleotide, which encodes the bacterial dnaJp1 peptide consisting essentially of SEQ ID NO: 4. Accordingly, Bardwell, et al. does not teach any isolated fragment within the full length nucleic acid sequence of Accession No. HHECDJ, let alone teach an isolated fragment of the nucleic acids at positions 181-225. Additionally, the cited reference does not teach or suggest a vector containing a polynucleotide sequence encoding a dnaJ peptide.

In re Application of:  
Carson and Albani  
Application No.: 09/616,247  
Filed: July 14, 2000  
Page 6

PATENT  
Attorney Docket No.: UCSD1370-5

Accordingly, Bardwell, et al. does not disclose every element of independent claim 10, and therefore does not disclose every element the claims that depend therefrom, Bardwell, et al. cannot anticipate the claimed invention and withdrawal of the rejection is therefore respectfully requested.

### Double Patenting Rejection

Applicants respectfully traverse the double patenting rejection of claims 10, 22 and 23 as allegedly unpatentable under the judicially created doctrine of obviousness-type double patenting, in light of the claims of U.S. Patent No. 5,773,570 (hereinafter "the '570 patent"). It is noted that the claims of the '570 patent are directed to a vaccine comprising an amino acid sequence of SEQ ID NO: 4. The claims of the present application, however are directed to an isolated *polynucleotide* which encodes a peptide of SEQ ID NO: 4 and to a gene expression vector which contains such a *polynucleotide*. (Emphasis added.) While the subject matter of both sets of claims is related to the sequence of SEQ ID NO: 4, the '570 patent is directed to a *peptide* having an amino acid sequence and the present claims are directed to a *polynucleotide* encoding SEQ ID NO: 4. Therefore the '570 patent and the present application are clearly not "both drawn to a composition containing a bacterial dnaJp1 peptide having the amino acid sequences of SEQ ID NO: 4," as alleged by the Examiner. Accordingly, it is respectfully submitted that the subject matter of the claimed invention is patentably distinct from and therefore patentable over the issued claims of the '570 patent and Applicants request withdrawal of the rejection.

In re Application of:  
Carson and Albani  
Application No.: 09/616,247  
Filed: July 14, 2000  
Page 7

PATENT  
Attorney Docket No.: UCSD1370-5


**CONCLUSION**

In summary, for the reasons set forth herein, Applicants maintain that claims 10, 18, 19, 22-24 and 32 clearly and patentably define the invention, respectfully request that the Examiner reconsider the various grounds set forth in the Office Action, and respectfully request the allowance of the claims which are now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (858) 677-1456. Please charge any additional fees, or make any credits, to Deposit Account No. 50-1355.

Respectfully submitted,

Date: December 2, 2003

  
Lisa A. Haile, J.D., Ph.D.  
Registration No. 38,347  
Telephone: (858) 677-1456  
Facsimile: (858) 677-1465

GRAY CARY WARE & FREIDENRICH LLP  
4365 Executive Drive, Suite 1100  
San Diego, California 92121-2133  
USPTO Customer Number 28213